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JN

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/533,895	09/26/95	TOPALIAN	S 2026-4205

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HM22/0125

EXAMINER

WEATHERSPOON, J

ART UNIT	PAPER NUMBER
1645	22

DATE MAILED: 01/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/533,895	Applicant(s) Topalian et al
	Examiner John K. Weatherspoon	Group Art Unit 1645

Responsive to communication(s) filed on Oct 29, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 64-93 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 64-93 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 19

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

1. Applicants' response and amendment dated October 29, 1998 in response to the Official Action mailed April 29, 1998 has been entered into the record. Claims 3-30, 56 and 61 have been cancelled. Claims 64-93 are pending. Claim 64 and newly submitted claims 65-92 (i.e. including dependent claims) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention as instantly claimed in said claims is not restricted to applicants' election of Group II, species A, as cited in applicants' response to the restriction requirement dated May 27, 1997 (Paper No. 11).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, said claims have only been examined to the extent that said claims are drawn to applicants' elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

2. Applicants' supplemental form PTO-1449 (Paper No. 19) dated November 2, 1998 was received and entered into the record. The examiner has considered all references including the reference for EMBL Accession No. M32295 as cited on the PTO-1449. Since the PTO-1449 listing for Genbank Database Accession No. M77348 cites the wrong month and year-- according to the reference provided, the correct month and year is January 8, 1995-- the examiner has corrected and initialed this listing on the PTO-1449.

Art Unit: 1645

Drawings

3. The drawings submitted with this application were declared informal by applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review. Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

Claim Objections

4. Claims 64-67, 69-79 and dependent claims thereof, i.e. claims 80-81, 83-87 and 89-92, are objected to because of the following informalities: the abbreviations "MHC" and "HLA-DR" should be replaced by the equivalent non-abbreviated terms. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 68 and dependent claims thereof, i.e. claims 71, 76, 79, 82, 85, 88 and 91, and claim 92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the following reasons: the specification fails to provide support for immunogenic peptide derivatives of tyrosine as instantly claimed in said claims.

Art Unit: 1645

6. The previous rejection of claim 64 under 35 USC 112, first paragraph is maintained for the reasons as stated in the Office Action mailed April 29, 1998. Further, in view of applicants' response (pages 7-8 of October 29, 1998 response) in which the only cited support for newly submitted claims 65-93 are original claims of the instant application which were previously rejected under 35 USC 112, first paragraph (see reasons as stated in the Office Action mailed April 29, 1998), *and since newly submitted claims 65-93 do not overcome said reasons as stated in the Office Action mailed April 29, 1998*, said reasons also serve as basis for rejection of newly submitted claims 65-93 under 35 USC 112, first paragraph.

Applicants' response (pages 8-11) dated October 29, 1998 has been fully considered. However, applicants' response is not persuasive to overcome said rejection under 35 USC 112, first paragraph. As stated in the previous Office Action mailed April 29, 1998, it is the Examiner's position that Lazar et al and Burgess et al demonstrate that a single amino acid change substitution will affect the biological activity of a protein. Thus it is reasonable for a skilled artisan in the art to conclude modifications of a peptide will affect the biological activity of said peptide. Furthermore, the art at the time of filing as exemplified by Salgaller et al. sets forth single amino acid or even side chain substitutions abrogate immunogenicity (T cell cytology). Additionally, Parker et al. concludes while the P2 and P9 residues of a nonamer peptide are of prime importance for peptide binding to HLA-A2, other peptide positions including P2, P3, P5-P7 and P9 were important for stable binding (see abstract). Finally,

Art Unit: 1645

Englehard states "studies have identified peptides that fail to bind or bind poorly despite the presence of an optimal motif" (see page 18; Column 1).

Since:

- 1) the quantity of experimentation necessary of the claimed invention requires screening a multitude of peptides
- 2) the art teaches of the unpredictability of single amino acid substitutions have on a protein (i.e. Salgaller et al., Burgess et al., and Lazar et al);
- 3) peptides fail to bind or bind poorly despite the presence of an optimal motif (see Englehard);
- 4) peptide positions including P2, P3, P5-P7 and P9 of nonamer peptide are important for stable binding (see Parker et al)

a skilled artisan would be forced into undue experimentation to practice the claimed invention (See *in re Wands*, 858 F.2d 731 8 USPQ2d 1400 (Fed. Cir. 1988).

In response to the previous Office Action, applicants urge the specification provides sufficient teachings for one skilled in the art to practice the claimed invention. These arguments are not considered persuasive. The decisional law has held the mere recitation in the specification of a broad concept does not necessarily provide a sufficient basis for broadly claiming it. See Ex parte Gardner 157 USPQ 162 (Bd. Pat. Apps and Interf. 1967), In re Cavallilo, 127 USPQ 202 (CCPA 1969). The fact that the terms in a claim are the same as those in the specification does not prevent the claims from being rejected as unduly broad if they define

Art Unit: 1645

subject matter not described to be the actual invention by means of adequate representative samples. See in re Lund, 153 USPQ 625 (CCPA 1967). In the instant case one skilled in the art **would be forced** into undue experimentation to practice the claimed invention. Due to the unpredictable nature of which modifications are useful (See Lazaret al., Burgess et al., Sallgaller et al., Parker et al. and Englehard) and the multitude of derivatives encompassed in the claimed invention one skilled in the art can not practice the invention as claimed absent undue experimentation.

69-79
7. ~~Claim~~ rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to *JKW 7-18-99* particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 69-76 recite the limitation "the immunogenic peptide". Claims 77-79 recite the limitation "the immunogenic peptide-MHC complex". There is insufficient antecedent basis for said limitations in said claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1645

9. Claim 93 is rejected under 35 U.S.C. 102(e) as being anticipated by either Boon et al (U.S. Patent No. 5,342,774 filed December 12, 1991; reference cited by applicants on Form PTO-1449), Ostrand-Rosenberg et al (US Patent No. 5858776 filed 11/3/93). Boon et al or Thanavala et al each disclose tumor associated antigens isolated by screening candidate antigens according to a method as stated in instant claim 93. The limitations of instant claim 93 are met by the prior art.

Status of Claims

10. No claim is allowed.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Weatherspoon, Ph.D. whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If

Art Unit: 1645

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (703) 308-3995.

John Weatherspoon, Ph.D.

January 18, 1999



Anthony Caputa, Ph.D.

Supervisory Primary Examiner

Group 1645